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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,169	03/24/2005	Young-Min Lee	26689U	2581

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,169	LEE ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12,15-25 and 29-37* is/are pending in the application.

4a) Of the above claim(s) *22-25* is/are withdrawn from consideration.

5)☒ Claim(s) *30-37* is/are allowed.

6)☒ Claim(s) *7-11,18-21 and 29* is/are rejected.

7)☒ Claim(s) *12 and 15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Jan. 21, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendments to the claims filed January 21, 2009 have been acknowledged and entered. Claims 7, 12, 15-18, 32 and 36 are currently amended.

Election/Restrictions

Applicant's arguments, see page 10, filed January 21, 2009, with respect to withdrawn claims 34-37 have been fully considered and are persuasive. The withdrawal of claims 34-37 has been withdrawn.

The restriction requirement for Group I to elect one sequence has been expanded to include two sequences. Therefore, SEQ ID NOs: 45 and 48 are under examination.

The restriction requirement, filed August 11, 2006, in regards to claims 22-25 is still deemed proper and is therefore made Final.

Status of the Claims

Claims 7-12, 15-25 and 29-37 are pending. Claims 22-25 have been withdrawn from consideration. Claims 7-12, 15-21 and 29-37 are under examination.

Specification

The amendment to the specification, filed January 21, 2009 has been entered.

Claim Objections

The objection of claim 12 because the claim contains multiple sequence identifiers, which are drawn to nonelected inventions **is withdrawn** pursuant Applicants amendments to the claim.

The objection of claim 15 because the claims contain multiple sequence identifiers, which are drawn to nonelected inventions **is maintained.** The claim currently contains SEQ ID NOs: 45, 47 and 48. Only SEQ ID NOs: 45 and 48 are under examination. Appropriate correction is required.

The objection of claims 16, 17, 31 and 32 because the claims contain vectors represented by SEQ ID NOs however, the sequence identifiers are not listed in the claims **is withdrawn**.

The objection of claim 38 **is moot** because the claim has been canceled.

Claim Rejections - 35 USC § 112

The rejection of claims 16 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn**. Applicants have amended the specification to include the address of the depository to remediate the rejection.

The rejection of claims 26 and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is moot** because Applicants have canceled the claims.

The rejection of claim 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is moot** because Applicants have canceled the claim.

The rejection of claims 7-11, 13-14, 18-21, 26-29 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector represented by SEQ ID NO: 45, pBAC^{SP6}/JVFLx/XbaI, comprising a full length infectious and genetically stable cDNA clone of JEV, does not reasonably provide enablement for a full length infectious and genetically stable cDNA clone of JEV **is withdrawn** pursuant Applicants amendments to claim 7.

Claim Rejections - 35 USC § 102

The rejection of claims 18-21, 26-28 and 38 under 35 U.S.C. 102(b) as being anticipated by Zhang et a. (Journal of Virological Methods, Aug. 2001, Vol. 96, No. 2, pages 171-182) **is withdrawn** pursuant Applicants amendments to claim 7 and the cancellation of claims 26-28 and 38.

New Objections

Specification

The disclosure is objected to because of the following informalities: Figure 3 includes sequences which are not properly identified by sequence identifiers. See 37 CFR § 1.821(d). Appropriate correction is required.

Claim Objections

Claim 12 is objected to because of the following informalities: The claim contains sequences which are not properly identified by sequence identifiers (i.e. No 48). See 37 CFR § 1.821(d). Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-11, 18-19, 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et a. (Journal of Virological Methods, Aug. 2001, Vol. 96, No. 2, pages 171-182) (see Office Action filed 9/4/2007) in view of Venugopal et al. (Vaccine, 1995, Vol. 13, No. 11, pages 1000-1005).

The claimed invention is drawn to a full length infectious and genetically stable cDNA of JEV, wherein the full length cDNA of JEV is cloned into a BAC vector, wherein the cDNA clone contains a promoter at the beginning of 5' end of a DNA sequence corresponding to a JEV

genomic RNA and a restriction endonuclease recognition sequence at the end of 3' end of the DNA sequence as a runoff site, wherein the promoter is SP6 of T7, wherein the restriction endonuclease recognition sequence does not exist in the JEV genomic RNA, wherein the infectious JEV RNA transcript is transcribed directly from the cDNA clone, wherein virus-unrelated nucleotides at its 3' end are removed, wherein the JEV genomic RNA consists of a 5' nontranslated region (NTR), a single polypeptide coding region and a 3' NTR. The claimed invention is also drawn to a cell transfected with the JEV RNA transcript.

Zhang et al. (hereinafter Zhang) teaches a technique to produce genome length cDNA stable clone from Japanese encephalitis virus (JEV) (Abstract). The cDNA has a T7 promoter at the 5' end and a "run-off" transcript with vector sequences at either end (Abstract). The full-length amplicon was cloned into a vector under the SP6 promoter (Abstract). The RNA transcript was synthesized from the clone (page 174-175, connecting paragraph). Zhang teaches RNA transcripts were transfected into BHK-21 cells (page 175, 1st column, 1st paragraph). Zhang teaches Japanese encephalitis virus has short untranslated regions (page 172, 1st column, 1st paragraph). Zhang teaches amplification of the full-length JEV genome by novel long RT-PCR protocol, transcription of infectious RNA directly from the amplicon and construction of a stable full-length JEV cDNA clone (page 173, 1st column, 2nd paragraph). Zhang also teaches the transcript from the clone was non-infectious, however, the transcript from the amplicon of the clone was infectious (page 180, top of 2nd col.). Therefore Zhang teaches the limitations of claim 29 because the JEV genome (Flavivirus) inherently encodes a single polypeptide coding region. Zhang does not teach the cDNA of JEV cloned into a BAC vector.

Venugopal et al. (hereinafter Venugopal) teaches protective immunogens of flaviviruses produced in a recombinant baculovirus expression system has been shown to be successful in animal models (Abstract). Venugopal teaches the cDNA clone was transcribed into the baculovirus vector (page 1001, 1st column, 2nd paragraph). Venugopal teaches the recombinant baculovirus vector expressing St. Louis encephalitis (SLE) virus proteins showed significant protective immune responses against SLE virus in mice (60% survival) (page 1003, 1st column, 2nd full paragraph). Therefore Venugopal teaches using a BAC vector with another encephalitis virus of the flavivirus family.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a baculovirus vector. The person of ordinary skill in the art would have been motivated to use a BAC vector because it is a common vector used in the art and Venugopal teaches the BAC vector provided protective immune response with a flavivirus, and reasonably would have expected success because of the teachings of Zhang and Venugopal.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Venugopal et al. as applied to claims 7-11, 18-19, 21 and 29 above, and further in view of Sumiyoshi et al. (Journal of Virology, 1992, Vol. 66, No. 9, pages 5425-5431) (see Office Action filed 9/4/2007).

The claimed invention is drawn to the invention described above wherein the virus-unrelated nucleotides are removed by treating mung bean nuclease (MBN). Neither Zhang nor Venugopal teach using mung bean nuclease to remove extra nucleotides.

Sumiyoshi et al. (hereinafter Sumiyoshi) teaches synthesis of infectious Japanese encephalitis virus (JEV) from JEV cDNA templates (Abstract). Sumiyoshi teaches digestion of ligation products were digested with mung bean nuclease to remove extra bases which were part of the restriction site to facilitate synthesis of the full-length viral RNA of JEV (page 5426, 2nd column 1st full paragraph).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to remove the extra bases from the restriction sites with mung bean nuclease. The person of ordinary skill in the art would have been motivated to use mung bean nuclease because Sumiyoshi teaches it is effective in cloning full-length JEV, and reasonably would have expected success because of the teaching of Zhang, Venugopal and Sumiyoshi.

Response to Arguments

Applicant's arguments filed January 21, 2009 have been fully considered but they are not persuasive. Applicant's arguments in reference to Zhang et al. will be addressed as they pertain to the new grounds of rejection. Applicants argue Zhang et al. do not teach "A full-length infectious and genetically stable cDNA clone of Japanese encephalitis virus (JEV), wherein a full length cDNA of JEV is cloned into a BAC vector." Applicants have amended the claims to include " wherein a full length cDNA of JEV is cloned into a BAC vector", therefore a new rejection is set forth *supra*. Applicants argue "Zhang et al. failed to establish a full length and genetically stable infectious cDNA clone of JEV." This argument is not persuasive with respect to the new rejection because Zhang clearly teaches a full-length cDNA was assembled by *in vitro*

ligation of two fragments digested with *Xho* I, from which as infectious transcript was obtained (page 178, 2nd column, 1st full paragraph, section 3.6).

Applicants cite Fernando et al. and Shizuya et al. (page 16 of Remarks) and emphasize that the BAC plasmid can be used to clone large DNA fragments. This argument is not found persuasive because it would be obvious to a person skilled in the art that if a BAC vector can encode large DNA fragments then it can also encode DNA fragments of lesser size. Applicants argue "that to acquire a genetically stable full-length infectious JEV cDNA clone was very difficult (see specification page 20, line 7-20)." This argument is not persuasive because Zhang was able to obtain an infectious full-length cDNA of JEV as discussed *supra*. Applicants argue "that the Examination Division of the EPO has acknowledged novelty and inventive step of the present invention." The Examination Report by the EPO Examination Division has been noted, however the EPO Examination is not-binding in the US.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Claims 12 and 15-17 are free of the prior art. However, claims 12 and 15-17 are objected to as depending from rejected claims. Claims 30-37 are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M, T, Th, F 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

April 9, 2009

/Zachariah Lucas/

Primary Examiner, Art Unit 1648